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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed a motion to exclude the opinions of Robert Ritchie, Ph.D. Doc. 7316. The motion is fully briefed, and the parties agree that oral argument is not necessary. The Court will grant the motion in part.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. IVC filters, such as Bard's Simon Nitinol Filter ("SNF"), originally were designed to be implanted permanently. Because some patients need only temporary filters, however, medical device manufacturers such as Bard developed retrievable filters.

Bard retrievable filters are spider-shaped devices with multiple limbs fanning out from a cone-shaped head. The limbs consist of legs with hooks that attach to the IVC wall, and shorter curved arms that serve to catch or break up blood clots. Seven different

versions of Bard retrievable filters are at issue in this MDL – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali. Each of these filters is a variation of its predecessor. Bard first obtained Food and Drug Administration ("FDA") clearance to market the Recovery in 2003. The last-generation Denali received FDA clearance in 2013.

Each Plaintiff in this MDL was implanted with a Bard filter and claims it is defective and has caused serious injury or death. Plaintiffs, among other things, allege that Bard filters are more dangerous than other IVC filters because they have a higher risk of tilting, perforating the IVC, or fracturing and migrating to vital organs. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that Bard filters are not defective and their overall complication rates are comparable to those of other IVC filters.

Plaintiffs have identified Dr. Ritchie, a mechanical engineer and materials scientist, as an expert witness on the design and manufacture of certain Bard filters. Dr. Ritchie received a bachelor's degree in physics and metallurgy, a master's degree in materials science, and a doctorate degree in materials science, all from Cambridge University. He has taught engineering courses at Massachusetts Institute of Technology, and currently teaches materials science as a distinguished professor at the University of California, Berkeley. He is a member of prestigious science and engineering academies, has published hundreds of peer-reviewed articles in the technical literature, and is highly regarded for his research in the fields of fatigue and fracture mechanics. With respect to medical devices, Dr. Ritchie has testified before the FDA about device fatigue and fracture and has served as a consultant to leading manufacturers of medical implants. Docs. 7319-1 at 3, 7319-2 at 49-50.[1]

[1] Page citations are to the numbers placed at the top of each page by the Court's electronic filing system.

Dr. Ritchie has authored a report assessing the structural integrity of Bard's G2, G2 Express, and Eclipse filters. He examined more than two dozen Bard filters that had experienced fractured limbs and other failures while implanted. Doc. 7319-1 at 3. He also reviewed internal Bard documents, medical records, medical and technical literature, other expert reports, and certain deposition testimony. *Id.* at 3-4. He opines that the fractures resulted from high cycle fatigue, which is the failure of a metal component over time due to cyclically varying physiological loading. *Id*. at 4, 25-30, 35-38. He further opines that contributing factors to the fatigue and resulting fractures include the lack of a chamfered filter head, poor surface conditions, rough grinding markings, and increased stress due to filter tilt and migration. *Id.*

Defendants do not challenge Dr. Ritchie's qualifications to opine about the manufacture and design of Bard filters from a technical perspective, nor do they seek to exclude his opinions about filter fatigue and fracture. Rather, Defendants ask the Court to exclude several categories of opinions: (1) Bard filters have "unacceptably high" complication rates; (2) one filter complication leads to others in a "vicious circle" of adverse events; (3) Bard's testing was insufficient; and (4) the SNF is a safer, alternative device. Doc. 7316 at 2. The Court will address each category.

II. Legal Standard.

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the

task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993).

III. Discussion.

A. Bard Filters Have "Unacceptably High" Complication Rates.

Dr. Ritchie opines in his report that Bard filters have "totally unacceptable failure rates." Docs. 7319-1 at 45, 7319-2 at 48. His rebuttal report states that the filters have an "unacceptably high incident of filter fractures." Doc. 7319-3 at 6. And he testified in his deposition that fracture rates are "particularly high" and "unacceptable." Doc. 7319 at 34. Defendants concede that Dr. Ritchie can testify about his own observations of filter fracture, but argue that any opinion about "high" or "unacceptable" complication rates should be excluded because Dr. Ritchie is not qualified to offer such opinions and has provided no reliable foundation for them. Doc. 7316 at 4-10. The Court agrees.

Dr. Ritchie's expertise is in the fields of mechanical engineering and materials science. He is not a medical doctor, biostatistician, or epidemiologist experienced in interpreting medical studies and data about device failure rates. Docs. 7319 at 43, 7319-4 at 4. And he has identified no other expertise or specialized knowledge that enables him to opine that Bard filters have unacceptably high complication rates.

Nor has Dr. Ritchie provided sufficient facts and data to support his opinions regarding filter complication rates, or identified any reliable principles and methods he used in forming such opinions. He testified that he read some small studies, but does not describe them or claim to have taken any steps to verify their conclusions. Doc. 7319 at 32-35. Plaintiffs themselves acknowledge that Dr. Ritchie's opinions "simply echo what is already reported in the literature." Doc. 7807 at 5. Dr. Ritchie stated that he uses the "unacceptably high" term "loosely" and only as a "personal statement" (Doc. 7319 at 33-34), and yet subjective personal beliefs are not appropriate expert opinions. *See Daubert*, 509 U.S. at 590 (noting that the word "knowledge" in Rule 702 "connotes more than subjective belief or unsupported speculation"); *In re Trasylol Prod. Liab. Litig.*, No. 08-MD-1928, 2010 WL 1489793, at *8-9 (S.D. Fla. Feb. 24, 2010) (excluding

opinions under Rule 702 where they were based on subjective beliefs rather than any objective standard or specialized knowledge).

Plaintiffs note that Dr. Ritchie relies on Dr. Betensky's opinions, and contend that such reliance is permissible to the extent those opinions satisfy the *Daubert* requirements. Doc. 7807 at 5. But even if Dr. Betensky's opinions about adverse event rates are reliable, Dr. Ritchie has taken no steps to verify her work. Doc. 7319 at 41. He read Dr. Betensky's report and mentions it briefly in the introduction of his report (Doc. 7319-1 at 6), but he concedes that he does not discuss her analysis further or rely on it for his opinions (Doc. 7319 at 40). Plaintiffs fail to explain how Dr. Ritchie's expertise in engineering or materials science support an opinion that filter complication rates are too high, and he never identifies the person or entity for whom the rates are unacceptable – physicians, patients, manufacturers, or the FDA.

Dr. Ritchie will not be permitted to opine that Bard filters have "high" or "unacceptable" complication rates.

B. The "Vicious Circle" of Filter Complications.

Dr. Ritchie concludes his report with this opinion about the synergistic effect of filter failure modes:

> *The "Vicious Circle":* Finally, it should be recognized that many of these adverse events or modes of failure are coupled. For example, a "vicious circle" can be created by the rough grinding markings, not polished out by Bard in the ankle regions of the legs, which clearly can result in fatigue fractures of the feet; such a loss of one or more "anchors" of the filter can make the device far more prone to tilting and/or migration, which can change the stress states and/or promote the possibility of penetrations/perforations of the filter struts through the vena cava, which in turn can increase the likelihood of fractures of the arms[.]

Doc. 7319-1 at 38. This opinion is unreliable, Defendants contend, because the only basis for it is Dr. Ritchie's intuition. Doc. 7316 at 10-12. The Court does not agree.

Relying on his knowledge and experience as a materials scientist and his examination of Bard filters and review of medical records, Dr. Ritchie sufficiently

describes the basis for his opinion that fracture and other failure modes can work synergistically. He explains in his report that the effect of a fractured leg would be to "de-anchor" the filter from the IVC wall and both increase the load on remaining intact legs, making them more susceptible to fracture, and lower the filter's resistance to tilt and migration. Doc. 7319-1 at 18, 24, 28, 37. He further explains that evidence from certain G2 filters he examined shows that perforation by filter arms (and to a lesser extent the legs) can promote the fracture of limbs because perforation significantly elevates stresses on the limbs and changes the magnitude and direction of the applied loading on the filter as a whole. *Id.* at 4, 25, 29-30, 37, 47.

When asked during his deposition about his opinion that tilt can lead to perforation, Dr. Ritchie provided this explanation:

> Some degree of tilt means that you have an anchor that's not anchored, and that means that the ability of the filter to move is obviously elevated because you're not fully anchored. Once the filter starts to move, the probability of perforation is likely, and all these things relate to the possibility of fracture and . . . that's what we talked about earlier with the crack growing in different directions. So I've always seen this as what I call a vicious circle. It's a synergy of events.

Doc. 7807-1 at 21; *see* Doc. 7319-1 at 47 (explaining that the different direction of fatigue cracks in filter arms is associated with perforation).

Defendants note that Dr. Ritchie is not able to identify with certainty the probability of one failure mode causing another, or predict which failure may occur first. Doc. 7316 at 10-11. But this lack of certainty does not require exclusion of his opinions under Rule 702. The Supreme Court has explained that "it would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty." *Daubert*, 509 U.S. at 590; *see also Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) ("Lack of certainty is not, for a qualified expert, the same thing as guesswork.").

Defendants also challenge Dr. Ritchie's opinions on the ground that he impermissibly relies on Dr. McMeeking's analysis of the strains caused by perforation. Doc. 7316 at 11. But Dr. Ritchie made clear that while his opinions are confirmed by

Dr. McMeeking's calculations, he did not rely on the calculations as the basis for his opinions. Doc. 7319 at 10-11.

Dr. Ritchie's opinion that different filter failure modes can have a synergistic effect on one another is sufficiently reliable and will not be excluded.

C. Bard's Testing Was Insufficient.

Defendants contend that Dr. Ritchie is not qualified to opine about Bard's testing, but do not explain why or otherwise identify the requisite expertise that may be lacking. Doc. 7316 at 12. Dr. Ritchie is a well qualified materials scientist who has been studying fatigue and material failure for nearly 50 years. He has worked with Nitinol since the late 1970s, and has evaluated various medical implants such as heart valves and stents. His testing experience includes protocol design and using test equipment in a laboratory environment. Doc. 7319 at 4. Dr. Ritchie is qualified to opine about Bard's testing of its IVC filters.

Defendants further contend that Dr. Ritchie employed no scientific or engineering methodology, claiming that he refers to Bard's testing only as "inadequate." Doc. 7316 at 12. To the contrary, Dr. Ritchie provides the basis for his opinions both in his report and his deposition testimony. He testified that his general criticism of Bard's testing is that it "never reproduced the problem when it comes to fracture." Doc. 7319 at 28. He expanded on this view by explaining that bench testing should simulate real life results:

> So the details of the test are almost less important, but if you've got a test where everything passes and yet you put it in people's bodies and things are happening, – you know, the actual implant in the body is the better test, and so your lab test is obviously not reflecting reality.

Id.; *see also* Doc. 7807-1 at 23 ("I've been critical of a lot of the tests that Bard did, because they never had a failure.").

In his report, Dr. Ritchie discusses two corrosion and fatigue tests Bard conducted on the Recovery filter. He finds the first one to be inadequate because "[t]oo few filters were tested, the test was too short (respiratory cycles are typically 15/min meaning that

[the] test simulated ~4 rather than 10 years), [and] it was conducted on one size filter (which may not have been the most highly stressed filter)." Doc. 7319 at 33. He opines that the most critical deficiency is that the test "did not simulate all modes of loading that the filter experiences *in vivo*" and was "never truly validated as no filters ever failed[.]" *Id.* He finds the second test to be deficient for similar reasons, explaining that the stress employed was "below the fatigue limit for [the] Nitinol wire, implying these test specimens would never fail, regardless of the number of loading cycles applied." *Id.* at 34. He further opines that no similar independent testing appears to have been performed for the G2 filter, and that Bard instead "relied on the same inadequate fatigue and corrosion testing performed on the Recovery." *Id.*

Bard disagrees with Dr. Ritchie's opinion that its testing was flawed because it failed to replicate filter failures (Doc. 8230 at 7), but this disagreement does not render his opinions unreliable for purposes of Rule 702. Bard will be free to cross examine Dr. Ritchie at trial. The Court will not exclude his opinions about Bard's testing.

D. The SNF is a Safer Alternative Filter.

Dr. Ritchie testified that the SNF is a safer filter than the Recovery and G2. Doc. 7319 at 42-44. The Court agrees with Defendants that Dr. Ritchie employed no reliable methodology in forming this opinion. Doc. 7316 at 13. As Plaintiffs concede, "his opinion regarding SNF is based on the statistical analysis performed by Dr. Betensky of SNF's adverse events relative to other Bard filters as well as studies in the published literature regarding comparative filter complication rates." Doc. 7807 at 9. But as explained above, Dr. Ritchie made no effort to verify Dr. Betensky's work, and mentions her analysis in his report only by way of background. Doc. 7319 at 41. Dr. Ritchie cannot simply repeat Dr. Betensky's opinions as his own.

Moreover, unlike Dr. McMeeking, Dr. Ritchie has performed no assessment of the SNF's design, manufacture, or structural integrity. *See* Doc. 7318-4 at 9-17. And he mentions the SNF only briefly in his report. Doc. 7319-1 at 15 (noting that the filter's original design drawings called for a 45º chamfer).

Plaintiffs have failed to establish a reliable foundation for Dr. Ritchie's opinion that the SNF is a safer, alternative filter. The opinion will be excluded.[2]

IT IS ORDERED that Defendants' motion to exclude the opinions of Robert Ritchie, Ph.D. (Doc. 7316) is **granted in part** as set forth in this order.

Dated this 8th day of February, 2018.

David G. Campbell
United States District Judge

[2] Defendants also assert that the opinions of Dr. Ritchie challenged in their motion will not assist the jury, but provide no explanation for this argument. Doc. 7316 at 3.